IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: PARAGARD IUD PRODUCTS LIABILITY LITIGATION	:	MDL DOCKET NO. 2974 1:20-md-02974-LMM
This document relates to: Pauline Rickard	:	CIVIL ACTION NOs.: 1:21-cv-03861-LMM

ORDER

This multi-district litigation ("MDL") involves the contraceptive Paragard, an intrauterine device ("IUD"), which is regulated as a drug under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., and the federal Food and Drug Administration's ("FDA") implementing regulations in Title 21 of the Code of Federal Regulations. The matter is now before the Court on Defendant's motion to exclude certain opinions of Labib Ghulmiyyah, M.D., as to the case of bellwether plaintiff Pauline Rickard ("Plaintiff").[1] Dkt. No. [51]. Upon due consideration, the Court enters the following Order.

I. BACKGROUND

Paragard is an IUD that is implanted into a patient's uterus by a healthcare provider. It is a T-shaped device that is made of polyethylene milled with barium

[1] "Teva" or "Defendant" refers collectively to Defendants Teva Pharmaceuticals USA, Inc.; Teva Women's Health, LLC; and Teva Branded Pharmaceutical Products R&D, Inc. Defendant CooperSurgical, Inc. ("Cooper"), which jointly filed the present motion with Teva, was granted summary judgment of Plaintiff's claims in other Orders. See Dkt. Nos. [116, 137, 138].

sulfate and wrapped in copper. It is indicated for intrauterine contraception for up to 10 years. The T-shape is designed to collapse for insertion and removal. It is supposed to be easy for a healthcare practitioner to remove the Paragard by gently pulling on attached threads.

Paragard has been approved and regulated by the FDA since 1984 without any significant design updates. Teva became the owner of the Paragard NDA in December 2008 and held it until the NDA was acquired by Cooper on November 1, 2017.

Plaintiff underwent placement of a Paragard by Richard Chlouber, M.D., in May 2012. At the time Plaintiff had her Paragard placed, there was nothing in the Warnings, Adverse Reactions, or Patient Information section of the label about Paragard breakage, and Plaintiff expected for the removal of her Paragard to be simple and easy. But when she had her Paragard removed by Niloufer Kero, M.D., in August 2021, the Paragard was broken, and Dr. Kero was not able to remove one arm of the Paragard. Dr. Kero sent Plaintiff for an ultrasound, which revealed that the missing Paragard piece was in Plaintiff's lower uterine cavity. Twelve days after the first attempt to remove the Paragard, Dr. Kero performed a hysteroscopy and dilation and curettage, while Plaintiff was under full anesthesia, to remove the remaining arm.

Dr. Ghulmiyyah is a board-certified obstetrician-gynecologist and maternal-fetal medicine specialist with over two decades of experience. He offers

the following expert-witness opinions in Plaintiff's case: (1) the Paragard label does not include a warning sufficient to apprise a reasonable physician of the risk of Paragard breakage; (2) Paragard breakage may cause significant injuries; (3) there is no evidence to indicate when Plaintiff's Paragard broke but that at the time of removal, it was broken; (4) there is no evidence to suggest that Plaintiff's Paragard broke due to physician error; and (5) the pain and suffering Plaintiff experienced as a result of surgery required to remove the fragments of the Paragard was more likely than not caused by the Paragard's propensity to break. Dkt. Nos. [42-2, 56-3].

II. LEGAL STANDARD

Rule 702 of the Federal Rules of Evidence governs the admissibility of proposed expert evidence:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

The trial court, as the evidentiary gatekeeper, must determine that the testimony is "sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 591 (1993) (cleaned up). The trial court must also "make certain that an expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999).

The Eleventh Circuit has synthesized the existing rules into a three-part inquiry, instructing courts to consider whether: (1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in Daubert; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue. City of Tuscaloosa v. Harcros Chems., Inc., 158 F.3d 548, 562 (11th Cir. 1998).

With regard to the second factor, the Supreme Court explained in Daubert and its progeny that courts should serve a gatekeeping function in order to ensure the reliability of the methods employed by expert witnesses. 509 U.S. at 589. The Daubert inquiry specifically addresses the reliability of an expert's principles and methods. Daubert lists factors for courts to consider, including: whether the theory or technique in question can be (and has been) tested; whether the theory

or technique has been subjected to peer review and publication; the known or potential rate of error; and general acceptance of the theory in the field. Daubert, 509 U.S. at 593-94. Additional factors courts have used to assess reliability of expert methods include whether the opinion naturally flowed from an expert's research or was developed specifically for litigation, and whether an expert has improperly extrapolated from a scientifically founded proposition to an unfounded conclusion. Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995); Allison v. McGhan Med. Corp., 184 F.3d 1300, 1312, 1314, 1321 (11th Cir. 1999).

But "expert testimony that does not meet all or most of the Daubert factors may sometimes be admissible." United States v. Brown, 415 F.3d 1257, 1268 (11th Cir. 2005). Indeed, reliability is meant to be a flexible inquiry for district courts, allowing them to determine which factors may be relevant and to apply only those factors which the court sees fit. United States v. Frazier, 387 F.3d 1244, 1262 (11th Cir. 2004). "The burden of laying the proper foundation for the admission of the expert testimony is on the party offering the expert, and admissibility must be shown by a preponderance of the evidence." Allison, 184 F.3d at 1306. However, "the proponent of the testimony does not have the burden of proving that it is scientifically correct, but that by a preponderance of the evidence, it is reliable." Id. at 1312.

The trial court has a great deal of flexibility in the inquiry into the reliability of an expert. Daubert, 509 U.S. at 595. This flexibility includes "latitude in deciding how to test an expert's reliability, and to decide whether or when special briefing or other proceedings are needed to investigate reliability." Kumho Tire, 526 U.S. at 152.

"In the end, although rulings on admissibility under Daubert inherently require the court to conduct an exacting analysis of the proffered expert's methodology, it is not the role of the district court to make ultimate conclusions as to the persuasiveness of the proffered evidence." Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd., 326 F.3d 1333, 1341 (11th Cir. 2003) (internal citations and quotation marks omitted). "Quite the contrary, '[v]igorous cross-examination, presentation of contrary evidence and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.'" Id. (quoting Daubert, 509 U.S. at 596) (alteration in Quiet Tech.).

III. DISCUSSION

Defendant argues that Plaintiff cannot meet her burden to establish the admissibility of Dr. Ghulmiyyah's case-specific opinions under Rule 702. The Court considers each of Defendant's arguments in turn.

A. Dr. Ghulmiyyah's warnings opinions

Defendant first argues that Dr. Ghulmiyyah's opinions as to the sufficiency of the warnings on the Paragard label will not be helpful to the jury because

Dr. Chlouber's testimony shows that he was already aware of the risk of breakage and that the warnings therefore could not have been the cause of Plaintiff's injuries. The Court does not agree.

The Court held in a separate Order that there are genuine issues of material fact as to whether the label adequately warned of the risk of breakage and whether Dr. Chlouber was already otherwise aware of the risk of breakage. Dkt. No. [149] at 7-12. Causation is therefore still at issue, and the adequacy of the label's warnings and the reasons the label's warnings may not have been adequate are still open questions. Dr. Ghulmiyyah's opinions regarding the sufficiency of the warnings therefore still apply under the facts of the case.

B. Dr. Ghulmiyyah's opinion regarding Plaintiff's concerns about future fertility

Dr. Ghulmiyyah describes Plaintiff's worries about her ability to conceive and opines that it is normal for patients to experience lasting concerns about fertility following unplanned OB/GYN complications such as the breakage and subsequent surgical removal of Plaintiff's Paragard. Dkt. No. [56-3] at 9. The Court agrees with Defendant that the testimony is excludable under Rule 702.

First, the article Dr. Ghulmiyyah cites as a basis for his opinion that Plaintiff's trauma and concerns about fertility are normal is based on a study of the levels of posttraumatic stress, depression, and anxiety in women in the nine months after early pregnancy loss, with a focus on miscarriage and ectopic pregnancy. See Farren, J., et al., Posttraumatic Stress, Anxiety and Depression

Following Miscarriage and Ectopic Pregnancy: A Multicenter, Prospective, Cohort Study, Am. J. of Obstetrics and Gynecology 222, no. 4 (Apr. 2020), available at https://doi.org/10.1016/j.ajog.2019.10.102. These circumstances are so different from the case at hand, the Court is not persuaded that the opinion has a proper foundation. As such, there is no reason for Dr. Ghulmiyyah to repeat Plaintiff's concerns about her ability to conceive. Dr. Ghulmiyyah therefore will be limited from testifying about Plaintiff's subjective concerns about her future fertility and whether the concerns are reasonable.

C. Dr. Ghulmiyyah's testimony on complications that are not alleged in this case

Defendant also moves to prevent Dr. Ghulmiyyah from testifying about certain events that can complicate removal of a broken IUD, including the possible need for abdominal surgery (laparoscopy or laparotomy) or even hysterectomy. Defendant argues that these complications are not relevant because Plaintiff did not suffer from them. Defendant further contends that the testimony would be inflammatory, would serve no purpose other than to engage juror sympathy or ire, and may leave the jury with the incorrect impression that these complications are still a risk for Plaintiff, despite the removal procedure having taken place four years ago.

The Court explained in a separate Order that the potential harms from broken IUD removals may be relevant as to emotional distress damages and the magnitude of danger in a failure-to-warn claim. Dkt. No. [144] at 17. In

considering whether a breakage warning is adequate, it is important to understand why breakage can lead to adverse consequences and where the warning should be in the label. Information regarding potential complications is also admissible because Plaintiff was informed of them before her surgery, and they therefore provide additional context to her damages.

However, Dr. Ghulmiyyah's testimony should be clear that it is not to show that Plaintiff actually has or will have these complications. If necessary, the Court may issue a limiting instruction.

IV. CONCLUSION

Defendant's motion to exclude certain opinions of Labib Ghulmiyyah, M.D., as to the case of bellwether plaintiff Pauline Rickard, Dkt. No. [51], is **GRANTED IN PART AND DENIED IN PART**, as set out above.

IT IS SO ORDERED this 6th day of January, 2026.

Leigh Martin May
Chief United States District Judge